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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/277,064	03/26/1999	LINDA A. SHERMAN	TSRI.433.1-D	3058

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EXAMINER	
DAVIS, MINH TAM B	

ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 11/16/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/277,064	SHERMAN, LINDA A.	
	Examiner	Art Unit	
	MINH-TAM DAVIS	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 September 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 61-75* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 61-75* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Accordingly, claims 1, 61-75 are being examined.

Claim Rejections - 35 USC § 112, First Paragraph, Written Description

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 61-68, 73, 75 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The response asserts that amendment of claim 61 to recite " a polypeptide with the amino acid sequence SEQ ID NO:12", and of claims 66, 68, 73, 75 to replace "comprises" with "is" obviates the rejection.

The response has been considered, but is not found to be persuasive.

The language " a polypeptide with the amino acid sequence SEQ ID NO:12" reasonably reads on " a polypeptide comprising the amino acid sequence SEQ ID NO:12", which is an open language. That is, the claims encompass a method for treating neoplasm, using a genus of polypeptides comprising sequences of unknown structure attached to the 10 amino acid peptide

SEQ ID NO:12. Similarly, the language "is" encompasses the same meaning as the open language "comprises".

The specification does not describe a polypeptide "with" SEQ ID NO:12, the polypeptide "is" SEQ ID NO:9, or the component "is" P3SCC in a manner that satisfies either the standards as shown in the example of Lilly or Enzo. The specification fails to describe a "representative number" of such species. In addition, the specification also does not describe "structural features common to the members of the genus, which features constitute a substantial portion of the genus.", nor a correlation between structure and function.

Claim Rejections - 35 USC § 112, First Paragraph, Scope of Enablement

Claims 1, 61-75 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for activating specific cytotoxic T lymphocytes in vivo in an animal having a "breast cancer that overexpresses" a Her-2/Neu protein, or a method for treating "a breast cancer that overexpresses" a Her-2/Neu protein, comprising administering a polypeptide "consisting of" SEQ ID NO:12, wherein a second component "consisting of" P3CSS or a second polypeptide "consisting of" SEQ ID NO:9 could be also administered, does not reasonably provide enablement for a method for activating specific cytotoxic T lymphocytes in vivo in an animal having "a **neoplasm**" that overexpresses a Her-2/Neu protein, or a method for treating **"a neoplasm"** that overexpresses a Her-2/Neu protein, comprising administering a polypeptide **"with"** SEQ ID NO:12, wherein a second component **"is" P3CSS** or a second polypeptide **"is"** SEQ ID NO:9 could be also administered. The

specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The response asserts that amendment of the claims obviate the rejection. Claims 1 and 61 are amended to replace "malignant cells" or "tumor" with " a neoplasm". Further, claim 61 is amended to recite " a polypeptide with the amino acid sequence SEQ ID NO:12", and of claims 66, 68, 73, 75 are amended to to replace "comprises" with "is".

The response has been considered, but is not found to be persuasive.

Claims 1, 61-75 encompass a method for **treating any type of abnormal growth** that overexpresses Her-2/Neu, which is not necessarily cancer, in view that "a neoplasm" encompasses any enlargement or abnormal growth, which is not necessarily cancerous (Stedman's medical dictionary, 25th ed, 1990, p. 1029-1030). One cannot predict that the claimed method would be successful in treating any abnormal growth that overexpresses Her-2/Neu, because different diseases have different etiology and characteristics, and do not predictably response to the same drug.

Further, claims 1, 61-75 encompass a method for treating any type of cancers that overexpress Her-2/Neu. One cannot extrapolate from treating a single cancer, breast cancer that overexpresses Her-2/Neu, to treating any other type of cancers that overexpress Her-2/Neu, because different cancers have different etiology and characteristics, and do not predictably response to the same drug.

In addition, one cannot predict that the peptide SEQ ID NO:12 is even exposed on the surface of the claimed polypeptide "with" SEQ ID NO:12, such that it is recognized by CTLs specific for SEQ ID NO:12, because SEQ ID NO:12 is only 10 amino acid in length, and

because of the unknown effect of the attached sequences to the conformation and function of the claimed polypeptide, in view of the teaching in the art that a protein conformation or its three-dimensional structure and its function depend on its amino acid composition, as taught by Bowie et al (Science, 1990, 257:1306-1310, of record). Similarly, in view of the teaching of Bowie et al, one cannot predict whether the claimed polypeptide comprising SEQ ID NO:9 or P3CSS would function as claimed.

Given the above unpredictability, and in view of the complex nature of the invention, and a lack of sufficient disclosure in the specification, it would be undue experimentation for one of skill in the art to practice the claimed invention.

Claim Rejections - 35 USC § 102(b)

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 61-67, 69-74 remain rejected under 35 U.S.C. 102(b) as being anticipated by Grey H M et al (WO 94/20127, 09/15/1994, of record).

1) The response asserts that the 102(b) rejection is improper, because the instant application claims, as priority, PCT/US 95/16415, which in turn claims, as priority, US 08/355,558, filed December 14, 1994, whereas Grey et al is published on September 15, 1994.

The response has been considered, but is not found to be persuasive.

The bibliographic data sheet only shows that this application claims as priority a divisional application 08/860,232, filed 08/08/1997. Applicant is invited to point out to which communication requested that the instant application also claims as priority PCT/US 95/16415, which in turn claims, as priority, US 08/355,558, filed December 14, 1994.

2) The response asserts that Grey et al do not teach every element of the instant invention, i.e. the use of a peptide to specifically activate CTLs in an animal having a neoplasm that overexpresses Her-2/neu.

The response further asserts that Grey et al is not an enabling disclosure. The response asserts that there is no evidence or experimental data showing that that the peptide disclosed by Grey et al can specifically activates CTLs in an animal. The response asserts that at most the teaching of Grey et al suggests that the peptide can bind to HLA-A2.1.

It is noted that neoplasm encompasses any abnormal growth, including cancer.

The response has been considered, but is not found to be persuasive.

Grey et al teaches that a pharmaceutical composition comprising the peptide of the invention is administered to a patient already suffering from cancer to elicit an effective CTL response to the tumor antigen, to cure or at least partially arrest symptoms and/or complications (p.22, lines 5-15). Grey et al teaches that examples of diseases include prostate cancer, renal carcinoma, cervical carcinoma, lymphoma (p.21, last paragraph, bridging p.22).

Although Grey et al do not explicitly teach that that human prostate cancer, cervix carcinoma, and kidney carcinoma overexpress Her-2/neu, however, the human prostate cancer, cervix carcinoma, and kidney carcinoma, all inherently overexpress c-erb-2, which is the same as Her-neu-2/neu, as evidenced by Gu K et al, Cancer letters, Feb 6, 1996,99(2): p185-9; Costa MJ

et al, American J Clin Pathol,1995, v.104, n.6, p:634-642; and Danova M et al, European journal of histochemistry, 1992, 36(3): p279-88, all of record. In other words, human prostate cancer, cervix carcinoma, and kidney carcinoma are species of the genus neoplasm that overexpresses Her-2/Neu.

Thus, although the art does not explicitly teach that the treated cancer is a neoplasm that overexpresses Her-2/Neu, however, the neoplasm to be treated in the claimed method appears to be the same as the prior art treated cancer. The office does not have the facilities and resources to provide the factual evidence needed in order to establish that the product of the prior art does not possess the same material, structural and functional characteristics of the claimed product. In the absence of evidence to the contrary, the burden is on the applicant to prove that the claimed product is different from those taught by the prior art and to establish patentable differences. See In re Best 562F.2d 1252, 195 USPQ 430 (CCPA 1977) and Ex parte Gray 10 USPQ 2d 1922 (PTO Bd. Pat. App. & Int. 1989).

Further, although the art is silent concerning the actual data on the effect of administrating the peptide pharmaceutical composition into patients having prostate cancer, cervix carcinoma, or kidney carcinoma, however, because the method of the prior art comprises the same method steps as claimed in the instant invention using the same composition, the claimed method is anticipated because the method will inherently lead to the claimed effects. See Ex parte Novitski 26 USPQ 1389 (BPAI 1993).

Moreover, this is a 102 rejection, and the status of a 102 rejection only requires that "the invention was patented or **described** in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent

in the United States". Thus the argument concerning the lack of the experimental data in Grey et al is moot.

NEW REJECTION BASED ON THE AMENDMENT

Claim Rejections - 35 USC § 112, Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 61-68 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 61-68 are indefinite for the use of the language "a polypeptide **with** the amino acid sequence" SEQ ID NO:2 in claim 61. It is not clear whether Applicant means "administering another polypeptide together with SEQ ID NO:12" or "administering a polypeptide comprising SEQ ID NO:12".

Proper amendment of the claims is required.

Conclusions

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MINH-TAM DAVIS whose telephone number is 571-272-0830. The examiner can normally be reached on 9:00 AM-5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, JEFFREY SIEW can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MINH TAM DAVIS
November 08, 2006

JEFFREY SIEW
SUPERVISORY PATENT EXAMINER